Proposed Registration Decision PRD2010-15

Pyroxsulam

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Overview

Proposed Registration Decision for Pyroxsulam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Pyroxsulam Technical Herbicide and Simplicity Herbicide, containing the technical grade active ingredient pyroxsulam, to control broadleaf and grassy weeds in spring wheat and durum wheat using ground or aerial application equipment.

Pyroxsulam Technical Herbicide (Registration Number 28886) and Simplicity Herbicide (Registration Number 28887) are conditionally registered in Canada. The detailed review for Pyroxsulam Technical Herbicide and Simplicity Herbicide can be found in Evaluation Report ERC2010-04, *Pyroxsulam*. The current applications were submitted to convert Pyroxsulam Technical Herbicide and Simplicity Herbicide from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Pyroxsulam Technical Herbicide and Simplicity Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on pyroxsulam, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on pyroxsulam, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation in this consultation document and within Evaluation Report ERC2010-04, *Pyroxsulam*.

What Is Pyroxsulam?

Pyroxsulam is the active ingredient in the end-use product Simplicity Herbicide. Simplicity Herbicide is a postemergence herbicide, i.e., a herbicide applied after the crop has emerged from the ground, which is registered to spring wheat and durum wheat using ground or aerial application equipment to control broadleaf and grassy weeds. Pyroxsulam inhibits the plant enzyme acetolactate synthase (ALS) in target weeds.

Health Considerations

How Approved Uses of Pyroxsulam Affect Human Health

Pyroxsulam is unlikely to affect your health when used according to the label directions.

Exposure to pyroxsulam may occur through diet (food and water), or when handling or applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

much higher) than levels to which humans are normally exposed when products containing pyroxsulam are used according to label directions.

Both the technical grade active ingredient, Pyroxsulam Technical Herbicide, and the end-use product, Simplicity Herbicide, are considered to be potential skin sensitizers; consequently, the label statement "Potential Skin Sensitizer" is required. The end-use product, Simplicity Herbicide, was considered to be of slight acute toxicity by the inhalation route and moderately irritating to eyes and skin, resulting in the requirement for the label statements "Warning Poison" and "Eye and Skin Irritant".

Pyroxsulam was not genotoxic and did not cause cancer in animals. There were no indications that pyroxsulam caused damage to the developing fetus, the reproductive system, or the nervous system. Health effects in animals given daily doses of pyroxsulam over long periods of time included effects on the liver.

A risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (e.g., children and nursing mothers). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Dietary risks from food and water are not of concern

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most pyroxsulam relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyroxsulam is not of concern for all population sub-groups. The lifetime cancer risk from the use of pyroxsulam on wheat is considered acceptable.

Animal studies revealed no acute health effects of pyroxsulam. No endpoint of concern attributable to a single dose was identified. Consequently, a single dose of pyroxsulam is not likely to cause acute health effects in the general population (including infants and children).

The Food and Drugs Act (FDA) prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for FDA purposes through the evaluation of scientific data under the Pest Control Products Act (PCPA). Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada using pyroxsulam on wheat were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation section of Evaluation Report ERC2010-04, *Pyroxsulam*.

Occupational Risks From Handling Simplicity Herbicide

Occupational risks are not of concern when Simplicity Herbicide is used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Simplicity Herbicide as well as field workers re-entering freshly treated fields can come in direct contact with Simplicity Herbicide residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Simplicity Herbicide must wear coveralls over a long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear. During mixing and loading, eye protection is also required. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, risk to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Pyroxsulam is Introduced Into the Environment?

Pyroxsulam can pose a risk to terrestrial and aquatic vascular plants, and the formulation Simplicity Herbicide can pose a risk to amphibians; therefore, spray buffer zones are required during application.

Pyroxsulam enters the environment when used as a herbicide on wheat. It is stable to hydrolysis but can phototransform in shallow, clear, water bodies. Pyroxsulam is non-persistent to slightly persistent in aerobic soil and in water. It is however considered persistent under anaerobic conditions. Pyroxsulam and its transformation products are expected to leach through the soil profile beyond 30 cm in some soils and therefore may be expected to enter groundwater. Based on Canadian field studies, residues of pyroxsulam and its transformation products are not expected to significantly carry over into the next growing season. Based on its low volatility, pyroxsulam residues are not expected in the air.

Pyroxsulam and its major transformation products present a negligible risk to wild mammals, birds, earthworms, bees and other arthropods, aquatic invertebrates, fish, and green algae. However, given that pyroxsulam is a herbicide, it is expected to adversely affect terrestrial plants in adjacent areas. Spray buffer zones of 2 metres for ground application and 55 to 65 metres for aerial application (depending on application equipment) are required to protect nearby terrestrial plants from the effects of spray drift. Pyroxsulam can potentially affect aquatic vascular plants in adjacent areas, while an aromatic petroleum distillate in the end-use product, Simplicity Herbicide, can potentially affect amphibians in adjacent areas. Therefore, a spray buffer zone of 1 metre is required to protect aquatic vascular plants and amphibians from the effects of spray drift.

Value Considerations

What Is the Value of Simplicity Herbicide?

Simplicity Herbicide, a postemergence herbicide, controls wild oats and broadleaf weeds in spring wheat and durum wheat.

A single application of Simplicity Herbicide provides effective control of a range of broadleaf weeds and wild oats in spring wheat and durum wheat. It is also compatible with integrated weed management practices and with conservation tillage and conventional crop production systems. Because Simplicity Herbicide is applied after weeds have emerged, producers can better assess whether the herbicide is necessary or suitable for particular weed species. Simplicity Herbicide provides an alternative to Group 1 herbicides, which are of concern given the spread of ACCase-resistant wild oats.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Simplicity Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Simplicity Herbicide on the skin, anyone mixing, loading and applying Simplicity Herbicide must wear coveralls over a long sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear. During mixing and loading, eye protection is also required. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Spray drift of pyroxsulam and the end-use product Simplicity Herbicide can pose a risk to terrestrial plants, aquatic vascular plants and amphibians. To mitigate the risk from the effects of spray drift, a buffer zone of 1 metre is required for the protection of sensitive freshwater habitats, and buffer zones of 2 to 65 metres, depending on the type of application equipment, are required to protect sensitive terrestrial habitats. These buffer zones are specified on the product label.

Other environmental concerns associated with pyroxsulam and Simplicity Herbicide are: the leaching potential of pyroxsulam and its transformation products; runoff; and the aromatic petroleum distillate present as a component in the formulation. These concerns are mitigated with label statements on the product label.

Next Steps

Before making a final registration decision on pyroxsulam, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please note that, to comply with Canada's international trade obligations, consultation on the proposed MRLs will also be conducted internationally via a notification to the World Trade Organization. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on pyroxsulam (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Pyroxsulam

1.0 The Active Ingredient, Its Properties and Uses

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of the active ingredient, its properties and uses. Analytical data from five batches of Pyroxsulam Technical Herbicide representing full-scale production were submitted to support the conversion to full registration of Pyroxsulam Technical Herbicide. The batch data support the specifications of the product.

A sample of chemical standard and a revised Statement of Product Specification Form (SPSF) containing the ISO common name of the active ingredient and the correct manufacturing plant location were also submitted in accordance with the Terms and Conditions outlined in the Section 12 notice associated with the original application for Pyroxsulam Technical Herbicide.

2.0 Methods of Analysis

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of the methods for analysis.

3.0 Impact on Human and Animal Health

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of the impact on human and animal health.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of the fate and behaviour in the environment. A log K_{ow} study with the transformation product, pyroxsulam sulfonamide, was submitted to support the conversion to full registration of Pyroxsulam Technical Herbicide. The log K_{ow} for pyroxsulam sulfonamide is 0.76, 0.78, and <0 in buffered solutions at pH 5, pH 7 and pH 9, respectively. Based on the log K_{ow}, the transformation product pyroxsulam sulfonamide is not expected to bioaccumulate in biological tissue.

4.2 Environmental Risk Characterization

4.2.1 Risks to Terrestrial Organisms

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of the risks to terrestrial organisms.

4.2.2 Risks to Aquatic Organisms

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of the risks to aquatic organisms. An acute toxicity study of pyroxsulam to the freshwater diatom, *Navicula pelliculosa*, was submitted to support the conversion to full registration of Pyroxsulam Technical Herbicide.

In a 96-hour acute static test, cultures of the freshwater diatom, *Navicula pelliculosa*, were exposed to pyroxsulam at mean measured concentrations of <LOQ (negative control), <LOQ (solvent control), 0.31, 0.66, 1.3, 2.5, 4.9, and 9.7 mg pyroxsulam/L. The 96-hour EC_{50} based on cell density, growth rate and yield was 3.9, 6.7, and 3.8 mg pyroxsulam/L, respectively (Appendix I, Table 1). The 96-hour NOEC for all endpoints was 2.5 mg pyroxsulam/L.

When Simplicity Herbicide is applied to wheat at the maximum application rate of 500 mL product/ha (15 g a.i./ha), pyroxsulam is not expected to pose a risk to the freshwater diatom, *Navicula pelliculosa* (Appendix I, Table 2).

4.2.3 Incident Reports

Since April 26, 2007, regist[illegible] effects to health and [illegible] reporting of [illegible] found on the Pesticide and Pest Management portion of Health C[illegible] ww.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php.

The PMRA is not aware of any incidents reported in the USEPA's Ecological Incident Information System (EIIS). The PMRA is aware of one minor Canadian incident report involving damage to non-target vegetation resulting from spray drift. Spray drift of Simplicity Herbicide can pose a risk to terrestrial plants. To mitigate the risk from the effects of spray drift, spray buffer zones of 2 to 65 [illegible] of application equipment, are required on the label to protect sensitive terrestrial habitats. Although the applicator did not observe the required 2 metre ground buffer zones, there was too much uncertainty and not enough information available to determine the cause of the damage. The PMRA concluded that the information from the Canadian incident report did not impact the risk assessment.

5.0 Value

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a detailed assessment of value.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for an assessment of the TSMP considerations. During the review of the application for conversion to full registration, the transformation product pyroxsulam sulfonamide was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- The transformation product pyroxsulam sulfonamide does not meet all Track 1 criteria, and therefore, is not considered a Track 1 substance. See Appendix I, Table 3 for comparison with Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for an assessment of the formulants and contaminants of health or environmental concern.

7.0 Summary

Refer to Evaluation Report ERC2010-04, *Pyroxsulam* for a summary of the impacts of pyroxsulam on human health and safety, the environmental risk of pyroxsulam, and the value of Simplicity Herbicide. The data submitted as a condition of registration indicate that pyroxsulam poses a negligible risk to the freshwater diatom, *Navicula pelliculosa*.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Pyroxsulam Technical Herbicide and Simplicity Herbicide, containing the technical grade active ingredient pyroxsulam, to control broadleaf and grassy weeds in spring wheat and durum wheat using ground or aerial application equipment.

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[5] DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

a.i.	active ingredient
ALS	acetolactate synthase
BAF	bioaccumulation factor
BCF	bioconcentration factor
cm	centimetre(s)
EC_{50}	effective concentration on 50% of the population
E_yC_{50}	effective concentration on 50% of the population based on yield
EIIS	Ecological Incident Information System
FDA	Food and Drugs Act
g	gram
h	hour(s)
ha	hectare(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOQ	limit of quantitation
mg	milligram(s)
mL	millilitre(s)
MRL	maximum residue limit
NOEC	no observed effect concentration
NOEL	no observed effect level
PCPA	Pest Control Products Act
PMRA	Pest Management Regulatory Agency
SPSF	Statement of Product Specification Form
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
v/v	volume per volume dilution

Appendix I Tables and Figures

Table 1 Toxicity to Non-Target Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference(s)
Freshwater species					
Diatom (*Navicula pelliculosa*)	96-h Acute	pyroxsulam	E_yC_{50}: 3.8 mg a.i./L NOEC: 2.5 mg a.i./L	No classification	PMRA 1752302

Table 2 Screening Level Risk Assessment on Non-Target Species

Organism	Exposure	Endpoint value and uncertainty factor[1]	EEC	RQ	Risk
Freshwater species					
Diatom (*Navicula pelliculosa*)	96-h Acute	$EC_{50} \div 2$: 1.9 mg a.i./L	0.0019 mg a.i./L	0.001	Negligible

[1] For characterizing acute risk, acute toxicity values (e.g., LC_{50}, LD_{50}, and EC_{50}) are divided by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (e.g., community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (e.g., 10 for fish, 2 for aquatic invertebrates). The difference in value of the uncertainty factors reflects, in part, the ability of certain organisms at a certain trophic level (i.e., feeding position in a food chain) to withstand, or recover from, a stressor at the level of the population. When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

Table 3 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value		Pyroxsulam Sulfonamide Endpoints
Toxic or toxic equivalent as defined by the Canadian Environmental Protection Act[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	212
	Water	Half-life ≥ 182 days	Not available
	Sediment	Half-life ≥ 365 days	Not available
	Air	Half-life ≥ 2 days or evidence of long range transport	Not available

TSMP Track 1 Criteria	TSMP Track 1 Criterion Value	Pyroxsulam Sulfonamide Endpoints
Bioaccumulation[4]	Log $K_{OW} \geq 5$	pH 5: 0.78 pH 7: 0.76 pH 9: <0
	BCF $\geq$ 5000	Not available
	BAF $\geq$ 5000	Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?		No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (i.e., all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over chemical properties (e.g., log K_{OW}).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1283061
Reference: 2005, Analytical method and validation for the determination of active ingredient and process impurities in XDE-742 technical by liquid chromatography, Data Numbering Code: 2.13.1 Confidential Business Information

PMRA Document Number: 1283063
Reference: 2005, Analytical method and validation for the determination of residual solvent in XDE-742 technical by gas chromatography, Data Numbering Code: 2.13.1 Confidential Business Information

PMRA Document Number: 1752299
Reference: 2008, Manufacturing plant location, Conditional to full registration, Pyroxsulam Technical Herbicide 28886, Data Numbering Code: 2.2 Confidential Business Information

PMRA Document Number: 1752300
Reference: 2009, Samples of analytical standards, Conditional to full registration, Pyroxsulam Technical Herbicide 28886, Data Numbering Code: 2.15

PMRA Document Number: 1876955
Reference: 2010, Batch analysis study for Pyroxsulam Technical [n-(5,7-dimethoxy[1,2,4] triazolo [1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide], Data Numbering Code: 2.13.3 Confidential Business Information

2.0 Environment

PMRA Document Number: 1752301
Reference: 2008, Octanol-water partition coefficient study, Data Numbering Code: 8.5

PMRA Document Number: 1752302
Reference: 2008, XDE-742 acute toxicity to the freshwater diatom (*Navicula pelliculosa*), Pyroxsulam Technical 28886, Data Numbering Code: 9.8.2